

**THIS PAGE IS INSERTED BY OIPE SCANNING
AND IS NOT PART OF THE OFFICIAL RECORD**

Best Available Images

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

BLACK BORDERS

TEXT CUT OFF AT TOP, BOTTOM OR SIDES

FADED TEXT

BLURRY OR ILLEGIBLE TEXT

SKEWED/SLANTED IMAGES

COLORED PHOTOS HAVE BEEN RENDERED INTO BLACK AND WHITE

VERY DARK BLACK AND WHITE PHOTOS

UNDECIPHERABLE GRAY SCALE DOCUMENTS

**IMAGES ARE THE BEST AVAILABLE
COPY. AS RESCANNING *WILL NOT*
CORRECT IMAGES, PLEASE DO NOT
REPORT THE IMAGES TO THE
PROBLEM IMAGE BOX.**

(19)



Europäisches Patentamt

European Patent Office

Office européen des brevets



(11)

EP 0 666 056 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention
of the grant of the patent:
27.10.1999 Bulletin 1999/43

(51) Int. Cl.⁶: A61B 5/029, A61B 5/0205

(21) Application number: 94101838.4 ✓

(22) Date of filing: 07.02.1994 ✓

(54) Method of assessing cardiovascular function

Verfahren zur Bestimmung der Herzgefäßfunktion

Procédé pour la détermination de la fonction cardiovasculaire

(84) Designated Contracting States:
DE ES FR GB IT NL SE
✓ ✓ ✓ ✓ ✓ ✓ ✓

(43) Date of publication of application:
09.08.1995 Bulletin 1995/32

(73) Proprietor: Perel, Azriel, Prof.
Tel-Hashomer 52621 (IL)

(72) Inventor: Perel, Azriel, Prof.
Tel-Hashomer 52621 (IL)

(74) Representative:
Kehl, Günther, Dipl.-Phys.
Patentanwaltskanzlei
Günther Kehl
Friedrich-Herschel-Strasse 9
81679 München (DE)

(56) References cited:

WO-A-87/06040

US-A- 3 831 590

US-A- 5 103 814

US-A- 5 188 098

- ANESTHESIA & ANALGESIA, vol.78, no.1, January 1994, BALTIMORE (US) pages 46 - 53
P.CORIAT ET AL. 'A Comparison of Systolic Blood Pressure Variations and Echocardiographic Estimates of End-Diastolic Left Ventricular Size in Patients After Aortic Surgery'
- ANESTHESIA AND ANALGESIA, vol.68, no.2, February 1989, BALTIMORE (US) pages 150 - 156
R.PIZOV ET AL. 'The Arterial Pressure Waveform During Acute Ventricular Failure and Synchronized External Chest Compression'

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Description

[0001] The invention relates to an apparatus by which the cardiovascular status of patients who are mechanically ventilated can be assessed by analyzing changes in hemodynamic parameters in response to predetermined changes in ventilation.

[0002] Cardiovascular function has to be frequently monitored in patients that are mechanically ventilated, either during anesthesia and surgery or due to some disease state. The aim of such monitoring is mainly to assess the adequacy of the blood volume status of the patient and to assess cardiac function. Cardiovascular function is being widely assessed by simply measuring the blood pressure and heart rate. However, these parameters alone are notorious for being too insensitive and too unspecific to assess and follow cardiovascular changes in sick patients.

[0003] There are some more advanced methods available of measuring cardiovascular function in patients who are mechanically ventilated. One of these methods is the measurement of the central venous pressure (CVP) by a catheter that is introduced through a vein into the right atrium or its vicinity (Ref. 1). The pressure in the right atrium (CVP), however, does not always reflect the pressure in the left side of the heart, i.e., the filling pressure of the left ventricle, which is the major blood pumping mechanism. Furthermore, the CVP may be elevated due to independent failure of the right heart or some lung disease, while the left atrial pressure is, in effect, low. Finally, estimating the filling volume of a heart chamber by measuring pressure is hindered by the compliance of that chamber.

[0004] A further method which is often used in critically ill patients or those who undergo major surgery is the introduction of a balloon-tipped pulmonary artery (Swan-Ganz) catheter. Thereby the pulmonary capillary wedge pressure (PCWP), which is an estimate of the left atrial pressure (Ref. 2), is measured. However, like the CVP, the PCWP is influenced by the compliance of the left ventricle. Furthermore, since the pulmonary circulation is situated between the tip of the catheter and the left atrium, high airway pressures during mechanical ventilatory support may cause a false elevation of the PCWP.

[0005] These problems and also the well-known pitfalls in the interpretation of filling pressures led to the practice that in patients who suffer from circulatory failure and in whom it is crucial to diagnose the pathological mechanism of such failure for further therapy, a graded fluid loading must be performed (Ref. 3). Such a procedure is very time-consuming and is not done very frequently.

[0006] It is also known that in addition to the pitfalls interpreting CVP and PCWP values, the insertion of CVP and especially of pulmonary artery catheters is costly, involves considerable training and associated with a multitude of reported complications (Ref. 2).

[0007] Another new technique for cardiovascular assessment is the so-called transesophageal echocardiography, which is an imaging technique that is mainly used for evaluating the size of the heart chambers and the status of myocardial contractility (Ref. 4). However, this method is also very costly, requires a lot of training, can be used for only one patient at a time, cannot be used continuously for longer periods of time, and is difficult to interpret in real time.

[0008] Furthermore, a method called pressure waveform analysis has been recently presented. According to this method, the changes in the systolic blood pressure during one mechanical breath cycle are clinically measured and used for cardiovascular assessment. Normally, the arterial pressure responds in a bi-phasic manner to a mechanical breath. An early increase in the systolic pressure (delta up, dUp) is caused due to transiently increased stroke volumes. The delta up is then followed by a decrease in the systolic pressure (delta down, dDown), which occurs due to the decrease in the amount of blood entering the right heart (venous return), due in turn to the increase in intrathoracic pressure during the mechanical breath. The difference between the maximal and minimal values of the systolic pressure during one mechanical breath is termed "systolic pressure variation" (SPV). It is known that the SPV and dDown are very sensitive indicators of the filling status and that they reflect this status better than PCWP and CVP (Ref. 5, 6, 7).

[0009] Recent studies have shown that pressure waveform analysis is a powerful tool in order to assess the cardiovascular status of mechanically ventilated patients. Therein SPV is measured in response to volume loads of human albumin infused to mechanically ventilated patients after abdominal aortic surgery. Performing pressure waveform analysis on the measured data provides reliable information concerning the preload of patients who have undergone vascular surgery (8).

[0010] It is an object of the present invention to provide a new apparatus for assessing cardiovascular function in ventilated patients which does not have the disadvantages of the methods used in the prior art as discussed above.

[0011] The new apparatus serves to assess the responsiveness of the patient to the administration of intravenous fluids, obviate the need for actual volume loading and the performance of invasive measurements that are currently used for such assessments.

[0012] This object is achieved by the apparatus as defined in the claims.

[0013] The respiratory maneuver of the invention is composed of a predetermined sequence of a few, preferably between 2 and 10, more preferably 2, 3, or 4, consecutive tidal volumes of varying magnitude, which will affect the filling of the heart in a graded manner. In general, these incremental changes in the airway pressure are used as a challenge to the cardiovascular system. The increase in airway pressure that is associated

with mechanical ventilation causes a series of changes in the filling and performance of the heart chambers.

[0014] The most important hemodynamic effects of such respiratory maneuver include normally:

- (a) a decrease in the venous return with relative emptying of the right atrium and ventricle, leading eventually to a transient reduction in left ventricular stroke outputs and a transient decrease in the systolic blood pressure;
- (b) an early increase in the filling of the left atrium and ventricle due to the squeezing of blood from the pulmonary vasculature. This increased preload causes an early transient increase in left ventricular stroke output during the mechanical breath;
- (c) a decrease in left ventricular afterload which may also augment left ventricular stroke output especially during congestive heart failure. The main mechanism of this phenomenon is the partial transmission of the increased airway pressure to the left ventricle and thoracic aorta relative to the subdiaphragmatic aorta.

[0015] Thus the normal response of the left ventricular stroke output to a mechanical breath is bi-phasic and includes an early increase followed by a later decrease.

[0016] More specifically, since the major cardiovascular effect of a mechanical breath is the reduction in venous return, a series of gradually increasing tidal volumes will cause a gradual decrease in venous return. The effects of this graded decrease in venous return on the cardiac output will be normally reflected by graded decreases in left ventricular stroke output and any physiological parameter that is influenced by it, e.g., arterial pressure, plethysmographic signal, Doppler signal, etc.

[0017] In addition, however, the respiratory maneuver may also induce respective increases in the hemodynamic variable (dUp), signifying the positive cardiovascular effect of increased airway pressure, which characterizes fluid overload with or without heart failure (Ref. 5, 8).

[0018] According to the invention, it is possible to measure the changes in the above parameters in response to the sequential respiratory maneuver. Such changes will be expressed by either absolute units, or preferably by percent changes of cardiovascular parameter per unit change in airway pressure or tidal volume (preset or measured).

[0019] The apparatus of the present invention performs a so called "respiratory systolic variation test" (RSVT).

[0020] It is also preferred that short apnea is induced prior to carrying out the respiratory maneuver described above.

[0021] The invention provides an apparatus for carrying out the above-described respiratory maneuver, namely in providing a few consecutive tidal volumes of varying magnitude, preferably after short apnea, and

monitoring the response of a hemodynamic variable to these tidal volumes of varying magnitude. The apparatus of the invention consists essentially of a respirator which is preferably linked to a monitor, said respirator and said monitor being preferably equipped with a specially designed software. The ventilator delivers, on demand or automatically, a series of tidal volumes of varying magnitude at a preset configuration and rate, preferably after short apnea. The size of these tidal volumes is not critical to the present invention and may be absolutely preset, set according to the patient's weight (e.g., 5, 10, 15 and 20 ml/kg), or pressure preset, i.e., the ventilator will be programmed to deliver tidal volumes according to varying degrees of preset pressures, preferably using a pressure controlled ventilation mode. Either the preset or the actually measured volumes or pressures may be used in the calculations.

[0022] The time difference between two tidal volumes and hence the time period for the total sequence is not critical either and can either be preset or chosen by those skilled in the art as required by the actual situation. For example, the time difference between two tidal volumes is in the range of 4 to 10 seconds and hence the total time period for the sequence of, e.g., four consecutive tidal volumes of varying magnitude is, e.g., in the range of 16 to 40 seconds.

[0023] The monitor will preferably be equipped with special software that will measure the changes in the hemodynamic parameter (e.g., blood pressure, plethysmographic signal, Doppler echo, etc.) during and following the variations of the airway pressure. The minimal systolic value of the signal of the chosen hemodynamic parameter will be recorded after each step of the airway maneuver, and a line of best fit can be plotted. The slope of that curve, which is the difference in the hemodynamic signal over the difference in airway pressure or volume, will be calculated and expressed according to the units of the measured parameter, e.g., mmHg of blood pressure/ml of tidal volume, mmHg blood pressure/cmH₂O of airway pressure, % change in systolic pressure/cmH₂O of airway pressure, % change in plethysmographic amplitude/ml of tidal volume, etc. The actual expired tidal volume or airway pressure can be preferably measured and plotted on the graph. Alternatively, the preset delivered tidal volumes or pressures can be used for plotting.

[0024] In addition to the minimal values mentioned above, the maximal values of the measured hemodynamic signal, e.g., maximal systolic blood pressure, after each breath will be preferably measured following each change in airway pressure. A curve depicting the slope of the change in that parameter relative to the change in tidal volume and/or airway pressure will be preferably plotted. The slope of this graph is a possible parameter assessing the degree by which an increase in airway pressure augments cardiac output.

[0025] Thus the two lines of best fit, that connecting the lowest values and that connecting the highest val-

ues, that are induced by the respiratory maneuver of the invention, create two angles relative to a reference horizontal line. The ratio of these angles to each other provides an additional parameter that reflects the status of intravascular filling and cardiac performance.

[0026] The airway pressure maneuver, i.e., the delivery of a few incremental volumes/pressures can be preferably incorporated into existing ventilators using either microprocessors or electronic technology or can be delivered by a stand-alone device. The main software for the monitoring of the Respiratory Systolic Variation Test (RSVT) can be located either in the monitor, respirator, or a separate device. The software and the monitor can accept information from the ventilator, e.g., the exact time of the start of each breath, the expired volume, the peak airway pressure, etc. After the start of each mechanical breath and during its cycle, the hemodynamic signal is tracked, and its minimal and maximal values are recorded throughout the test. The monitor is equipped to calculate and show the slopes of the minimal and maximal values of the hemodynamic parameter after the completion of the respiratory maneuver as well as the angles of the slopes of the change in maximal (upslope) and minimal (downslope) values and the ratio. It should also be possible to determine additional parameters such as the area under the curve, dp/dt_{max} (which is a measure of contractility), etc.

[0027] Preferably, the monitor is also equipped so as to calculate the systolic pressure variation (SPV), which is the difference between the maximal and minimal values of the hemodynamic physiological parameter, e.g., blood pressure, during one cycle of the mechanical breath. Preferably, the monitor is also able to show delta up and delta down, i.e., the degree by which the hemodynamic physiological parameter increases and decreases, respectively, in response to airway manipulation relative to its baseline during the preinspiratory period.

[0028] The apparatus of the invention can be used in all mechanically ventilated patients in whom a physiological parameter that reflects left ventricular stroke volume is continuously measured. It can serve as a basic diagnostic test apparatus for the determination of volume responsiveness, which is very high during frank hypovolemia and very low or negative during congestive heart failure and/or volume overload. It may be used in anesthetized patients and in all other patients that are mechanically ventilated by any ventilatory mode. With the apparatus of the present invention, it is hence possible to easily measure the cardiovascular status by medical equipment normally used in any mechanically ventilated patient without the need of additional complicated, costly and difficult-to-use equipment.

Figure 1 - is a schematic drawing of the principle of the invention.

Figure 2 - is an example of a possible respi-

ratory maneuver.

Figures 3a to 3d - show the steps of the analysis of the changes in the systolic pressure during the RSVT.

Figure 4 - is the trace of airway pressure during the respiratory maneuver (Fig. 4a) accompanied by a trace of the arterial blood pressure in a volume responsive state (Fig. 4b).

Figure 5 - shows the respiratory systolic variation test (RSVT) performed by the present invention in a hypovolemic patient.

Figure 6 - shows the angles of the RSVT in dog #1 (Fig. 6a) and dog #2 (Fig. 6b) subjected to bleeding, retransfusion and volume overload.

Figures 7a and 7b - show the graphic display of the changes in the downslope and upslope of the RSVT during a case of aortic surgery.

Figure 8 - shows the relation of the downslope of the RSVT and the CVP values during this procedure of aortic surgery.

Figure 9 - shows the change in the ratio of the angles of the upslope (Y) and downslope (X) at different CVP values.

Figure 10 - shows the response of the downslope to volume loading in 11 patients.

[0029] In the following the invention will be explained in more detail with reference to Figures 1-10.

[0030] Figure 1 is a schematic drawing explaining the principle of the present invention. In the lower part the airway pressure provided by a respirator is shown and the upper part illustrates the response of a hemodynamic variable, in which case the blood pressure is shown.

[0031] Between T_0 and T_1 normal ventilation is carried out. The response of the blood pressure is identical for each breath cycle (7 breath cycles are depicted between T_0 and T_1), showing only statistical variations. During each breath cycle the dUp and dDown in the blood pressure can be seen.

[0032] At T_1 short apnea is induced (optional), which ends at T_2 . It is evident that the blood pressure is constant during the apnea, not showing any dUp or dDown.

[0033] At T_2 the variation of the airway pressure is initiated, starting at an airway pressure of, e.g., 10 cmH₂O in the first breath cycle and increasing up to, e.g., 40 cmH₂O in the fourth breath cycle. In the upper part of Figure 1 the characteristic response of the blood pressure is shown. It is evident that the maximal values of the blood pressure during each breath cycle increase with increasing airway pressure and that the minimal values of the blood pressure during each breath cycle decrease with increasing airway pressure. In other words, the dependence of the dUp and dDown values on variations in airway pressure are shown.

[0034] At T_3 the variation of the airway pressure ends and a second short apnea (optional) is induced, leading to a constant blood pressure which can be used as a reference value for evaluating the effect of the airway pressure variation on the blood pressure.

[0035] At T_4 the short apnea ends and normal ventilation is continued.

[0036] Typical values for the time difference T_0 - T_1 are in the region of 25 to 50 seconds i.e. about 8 to 16 breaths/min. Typical values for the airway pressure during normal ventilation are in the region of 15 to 30 cmH₂O.

[0037] The maximal airway pressure which can be used during the variation of the airway pressure depends on the condition of the patient but is normally below 40 cmH₂O.

[0038] Figure 2 shows an example of a possible respiratory maneuver consisting of four consecutive breaths. The ventilatory mode used is pressure controlled ventilation at a rate of 8/min, I:E ratio 1:3. The respiratory maneuver in this example includes five levels of pressure, namely 0, 10, 20, 30 and 40 cmH₂O. The specific variables, i.e., the number of breaths, and the level and duration of pressure can be changed according to the circumstances and the condition of the patient or will be fixed in the apparatus. The zero pressure level (or the PEEP level) serves for the determination of the value of the hemodynamic parameter during apnea.

[0039] Figure 3a shows the response of a hemodynamic parameter (in this case the blood pressure) to a respiratory maneuver as shown in Figure 2. Figure 3b exemplifies the identification of the minimal (X) and maximal (Y) systolic values after each change in airway pressure, i.e. during each of the four cycles of mechanical breaths.

[0040] Figure 3c shows the lines of best fit for the minimal (X) and maximal (Y) values.

[0041] Figure 3d exemplifies the calculation of the slope of each line characterized by angle α for the downslope and angle β for the upslope. Downslope X is a measure of volume responsiveness while upslope Y is a measure of cardiac (stroke) output augmentation.

[0042] In Figure 4 a respiratory maneuver and the resulting changes in the arterial blood pressure which occur in a volume responsive normal patient are shown. The gradual significant decreases in the systolic pres-

sure after each breath (accounting for the steep line of best fit) are significant for the volume responsiveness of the patient.

[0043] Figure 5 shows how a hemodynamic variable (in this case also the blood pressure) responds to the respiratory maneuver of the present invention if the patient is very hypovolemic. The diagnosis of hypovolemia can be made by a skilled person by looking at the steepness of line X connecting the minimal systolic values (A,B,C,D). Even the slope of line Y, connecting the maximal values (1,2,3,4), is slightly negative, thus confirming the diagnosis of severe hypovolemia.

[0044] Figure 6 depicts an example of a possible analysis of the changes in the blood pressure curve following the respiratory maneuver of the present invention in two dogs during bleeding of 30% of estimated blood volume (A), retransfusion of shed blood (B), and additional volume overload (C). In this figure the Y axis is the % of change in the blood pressure at four levels of airway pressure (X axis). It can be clearly seen that depending on the volume states, slope α in equation $y = ax + b$ varies, the slope during hypovolemia being the steepest while the slope during volume overload being the flattest. Therefore, the slope of the hemodynamic variable during the respiratory maneuver allows a skilled person to decide whether fluid transfusion should be made in a patient having symptoms of impending circulatory failure, or whether a volume overload has already occurred, so that other therapeutic measures are necessary.

[0045] In Figures 7a and 7b the repetitive use of the RSVT performed by the present invention during aortic surgery is demonstrated. Points 1-13 denote the following intraoperative events:

1. Significant hypovolemia due to bleeding (prior to clamping);
2. immediately after aortic clamping;
3. several minutes after clamping during drop in blood pressure;
4. after infusion of one liter and during light anesthesia;
5. after addition of nitrous oxide;
6. additional volume replacement with blood and hemaecel;
7. following epidural injection of 25mg bupivacaine (Marcaine);
8. prior to unclamping;
9. dopamine infusion started prior to unclamping;
10. immediately after unclamping first leg;
11. immediately after unclamping second leg;
12. after bolus dopamine due to hypotension unresponsive to volume replacement; and
13. after addition of nitroglycerin (0.8mg/kg/min) and 25mg epidural bupivacaine (Marcaine) for hypertension.

[0046] Figure 7a depicts the change in the downslope

of the four minimal systolic values during the RSVT. The exaggerated volume responsiveness at points 1-4 and 13 can be clearly seen while points 7, 8, 10, 11 and 12 are characterized by a lack of change in the systolic blood pressure during the respiratory maneuver of the present invention, thereby denoting a non-volume responsive state and indicating that a skilled person that a blood transfusion would probably not be of too much use, while cardiotonic agents may improve cardiac function, if so desired.

[0047] Figure 7b depicts the change in the upslope, i.e., the maximal systolic values, during the RSVT. Points 10-12 are characterized by steep upslopes and flat downslopes from which a skilled person can take that the filling pressures are high and that possibly a significant reduction in cardiac contractility (heart failure) has occurred.

[0048] In Figure 8 the relation between the % change in the minimal systolic values during the method performed by the present invention and the CVP (a method of the prior art discussed above) during this case of aortic surgery is shown. The r value is -0.69 and actually closer to -1 if the outlier is disregarded. This shows a significant correlation between the CVP measured by the complicated methods of the prior art and the minimal systolic values easily measured by the present invention.

[0049] In Figure 9 events 1, 2, 9 and 11 of aortic surgery as explained in Figure 7 were used to show that the ratio between the angles of the downslope (X) and upslope (Y) change at different values of the central venous pressure (CVP). Low CVP values are associated with greater α_2 angles, which reflect hypovolemia, thereby giving a skilled person helpful means in establishing this diagnosis. It should be noted that the X-slope expressed by α_2 decreases and that the Y-slope (α_1) increases at higher CVP values.

[0050] Figure 10 shows the results of volume loading in 11 patients. In this graph the downslope on the X axis is the difference between the minimal systolic blood pressure after two breaths of 20 and 5 ml/kg, i.e. downslope = SBPmin20 - SBPmin5. The dDownslope on the Y axis is the change in the downslope after volume loading in 11 patients. The graph shows that higher baseline downslopes are associated with a more significant response to volume loading. The present invention can also be used to follow the effects of volume administration.

References:

[0051]

1. Kaye WE, Dubin HG: Vascular cannulation. in, Civetta JM et al, eds, Critical Care, JB. Lippincott, 1988, pp 214-219.
2. Clark CA, Hannan EM: Hemodynamic monitor-

ing: Pulmonary artery catheters. in, Civetta JP et al, eds., Critical Care, JB Lippincott, 1988, pp 293-6.

3. Majid PA, Roberts R Heart failure in, Civetta JM et al, eds., Critical Care, JB Lippincott, 1988, pp 948-952.

4. Konstadt S et al: Transesophageal echocardiography. in, Kaplan JA, ed, Cardiac Anesthesia, Saunders, 1993, p 364.

5. Perel A, Pizov R, Cotev S: The systolic pressure variation is a sensitive indicator of hypovolemia in ventilated dogs subjected to graded hemorrhage. Anesthesiology 67:498-502, 1987.

6. Pizov R, Ya'ari Y, Perel A: Systolic pressure variation is greater during hemorrhage than during sodium nitroprusside induced hypotension in ventilated dogs. Anesth Analg 67: 170-174, 1988.

7. Pizov R, Ya'ari Y, Perel A: The arterial pressure waveform during acute ventricular failure and synchronized external chest compression. Anesth Analg 68:150-150, 1989.

8. Coriat P, Vrillon M, Perel A et al: A comparison of systolic blood pressure variations and echocardiographic estimates of end-diastolic left ventricular size in patients after aortic surgery. Anesth Analg 78:46-53, 1994.

Claims

1. Apparatus for cardiovascular assessment in ventilated patients, comprising a ventilator for ventilating a patient and means for measuring hemodynamic parameters, characterized by
 - (a) said ventilator being designed to deliver at least a few tidal volumes or pressure levels of different magnitude,
 - (b) means for measuring the hemodynamic response to the variation of the tidal volumes or pressures, and optionally
 - (c) a calculating unit adapted to perform analytic calculations in response to said measured data.
2. An apparatus according to claim 1, characterized in that the calculating unit calculates the slope of the line of best fit of the peak or trough values of the hemodynamic response.
3. An apparatus according to claim 1 or claim 2, characterized in that the calculating unit calculates the area under the curve of said hemodynamic response in a certain region.

4. An apparatus according to claim 1, claim 2 or claim 3, characterized in that the calculating unit calculates the difference between the peak or trough values of said hemodynamic response and a reference value measured during a short apnea.
5. An apparatus according to anyone of the previous claims, characterized in that the means for measuring the hemodynamic response is adapted for measuring a parameter reflecting the left ventricular output.
6. An apparatus according to anyone of the claims 1 to 4, characterized in that the means for measuring the hemodynamic response is adapted for measuring the blood pressure.
7. An apparatus according to anyone of the claims 1 to 4, characterized in that the means for measuring the hemodynamic response is adapted for measuring the plethysmographic signal.
8. An apparatus according to anyone of the claims 1 to 4, characterized in that the means for measuring the hemodynamic response is adapted for measuring the Doppler or echo signals.
9. An apparatus according to anyone of the previous claims, characterized in that the means for measuring the hemodynamic response is adapted for continuously measuring.

Patentansprüche

1. Vorrichtung zur Bestimmung des Herz- und Gefäßzustands bei beatmeten Patienten, die ein Beatmungsgerät zur Beatmung eines Patienten und Mittel zum Messen hämodynamischer Parameter aufweist, dadurch gekennzeichnet, daß

(a) das Beatmungsgerät so beschaffen ist, daß wenigstens einige Hubvolumen oder Druckpegel unterschiedlicher Größe geliefert werden können,

(b) Mittel zum Messen der hämodynamischen Antwort auf die Variation der Hubvolumen oder Drücke, und im Bedarfsfall

(c) eine Recheneinheit, die analytische Berechnungen im Ansprechen auf die gemessenen Daten durchführen kann.

2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die Recheneinheit die Steigung der Mittelwertsausgleichsgerade der Maximal- oder der Minimalwerte der hämodynamischen Antwort berechnet.

3. Vorrichtung nach Anspruch 1, Anspruch 2, dadurch

gekennzeichnet, daß die Recheneinheit die Fläche unter der Kurve der hämodynamischen Antwort in einem bestimmten Bereich berechnet.

4. Vorrichtung nach Anspruch 1 oder Anspruch 2 oder Anspruch 3, dadurch gekennzeichnet, daß die Recheneinheit die Differenz zwischen den Maximal- oder den Minimalwerten der hämodynamischen Antwort und einem während einer kurzen Apnoe gemessenen Referenzwert berechnet.

5. Vorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Mittel zum Messen der hämodynamischen Antwort geeignet sind, einen Parameter zu messen, der den linksventrikulären Ausstoß wiedergibt.

6. Vorrichtung nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß die Mittel zum Messen der hämodynamischen Antwort zum Messen des Blutdruckes geeignet sind.

7. Vorrichtung nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß die Mittel zum Messen der hämodynamischen Antwort zum Messen des plethysmographischen Signals geeignet sind.

8. Vorrichtung nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß die Mittel zum Messen der hämodynamischen Antwort zum Messen der Doppler- oder Echosignale geeignet sind.

9. Vorrichtung nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß die Mittel zum Messen der hämodynamischen Antwort zur kontinuierlichen Messung geeignet sind.

Revendications

1. Dispositif d'évaluation cardio-vasculaire de patients ventilés, comprenant un ventilateur destiné à ventiler un patient et un moyen destiné à mesurer des paramètres hémodynamiques, caractérisé en ce que :

(a) ledit ventilateur est conçu pour délivrer au moins quelques volumes ou niveaux de pression d'air de respiration de grandeurs différentes,

(b) un moyen destiné à mesurer la réponse hémodynamique à la variation des volumes, ou pressions, d'air de respiration, et de façon optionnelle,

(c) un module de calcul susceptible d'effectuer des calculs analytiques en réponse auxdites données mesurées.

2. Dispositif selon la revendication 1, caractérisé en

12

ce que le module de calcul calcule la pente de la ligne de meilleur ajustement des valeurs de pic, ou de creux, de la réponse hémodynamique.

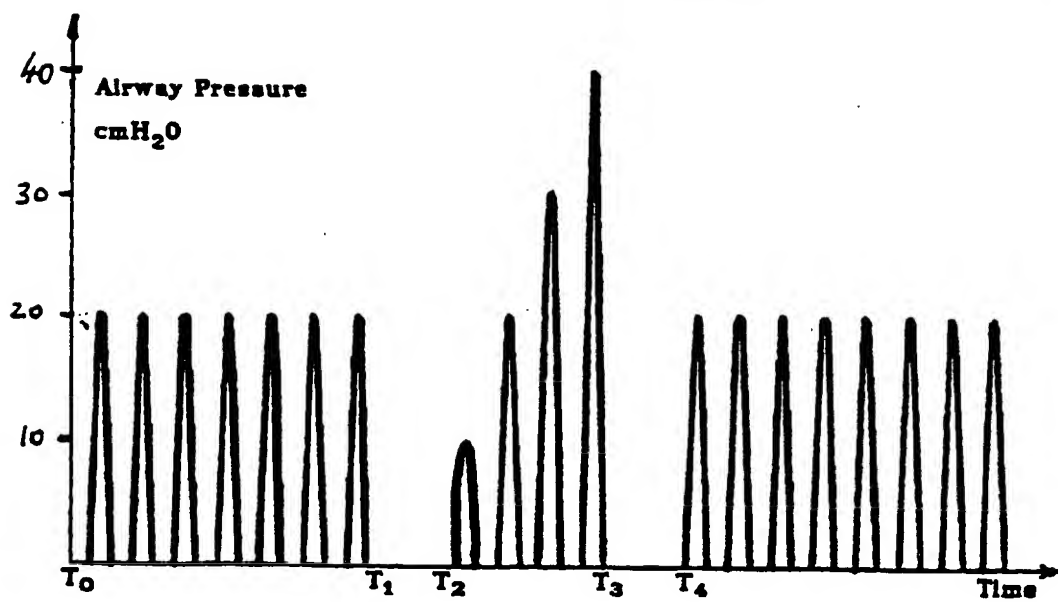
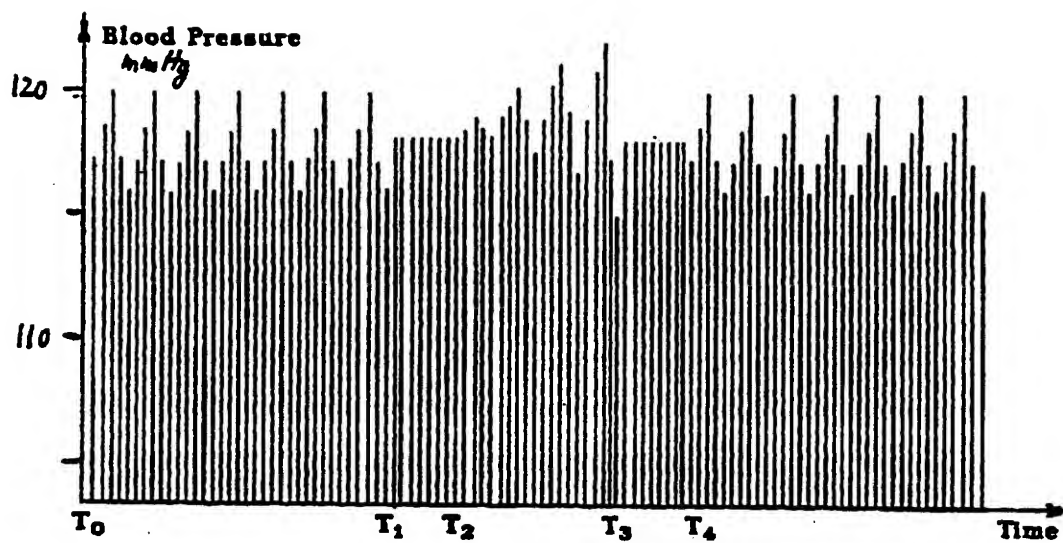
3. Dispositif selon la revendication 1 ou la revendication 2, caractérisé en ce que le module de calcul calcule l'aire qui se trouve sous la courbe de ladite réponse hémodynamique dans une certaine région. 5
4. Dispositif selon la revendication 1, la revendication 2 ou la revendication 3, caractérisé en ce que le module de calcul calcule la différence entre des valeurs de pic, ou de creux, de ladite réponse hémodynamique et une valeur de référence mesurée pendant une courte période. 10 15
5. Dispositif selon l'une quelconque des revendications précédentes, caractérisé en ce que le moyen de mesure de la réponse hémodynamique est adapté à mesurer un paramètre reflétant la sortie ventriculaire gauche. 20
6. Dispositif selon l'une quelconque des revendications 1 à 4, caractérisé en ce que le moyen de mesure de la réponse hémodynamique est adapté à mesurer la pression sanguine. 25
7. Dispositif selon l'une quelconque des revendications 1 à 4, caractérisé en ce que le moyen de mesure de la réponse hémodynamique est adapté à mesurer le signal pléthysmographique. 30
8. Dispositif selon l'une quelconque des revendications 1 à 4, caractérisé en ce que le moyen de mesure de la réponse hémodynamique est adapté à mesurer des signaux de Doppler ou d'écho. 35
9. Dispositif selon l'une quelconque des revendications précédentes, caractérisé en ce que le moyen de mesure de la réponse hémodynamique est adapté à effectuer une mesure continue. 40

45

50

55

FIG 1



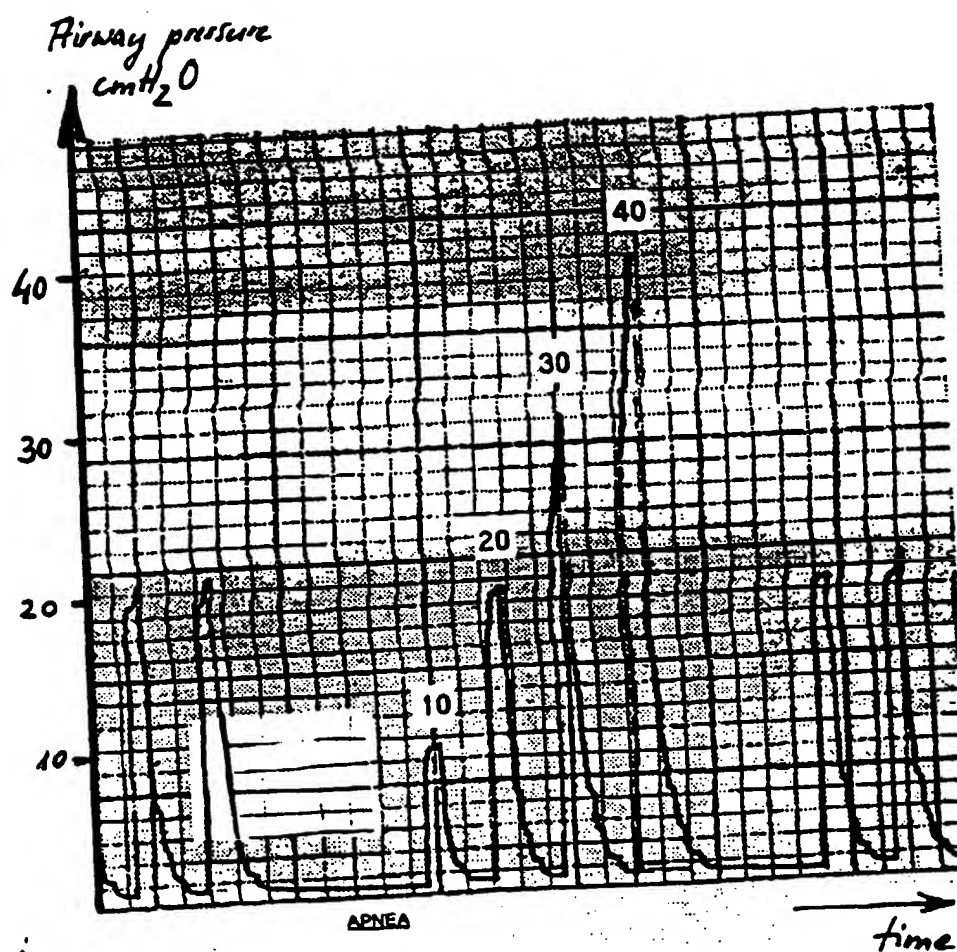
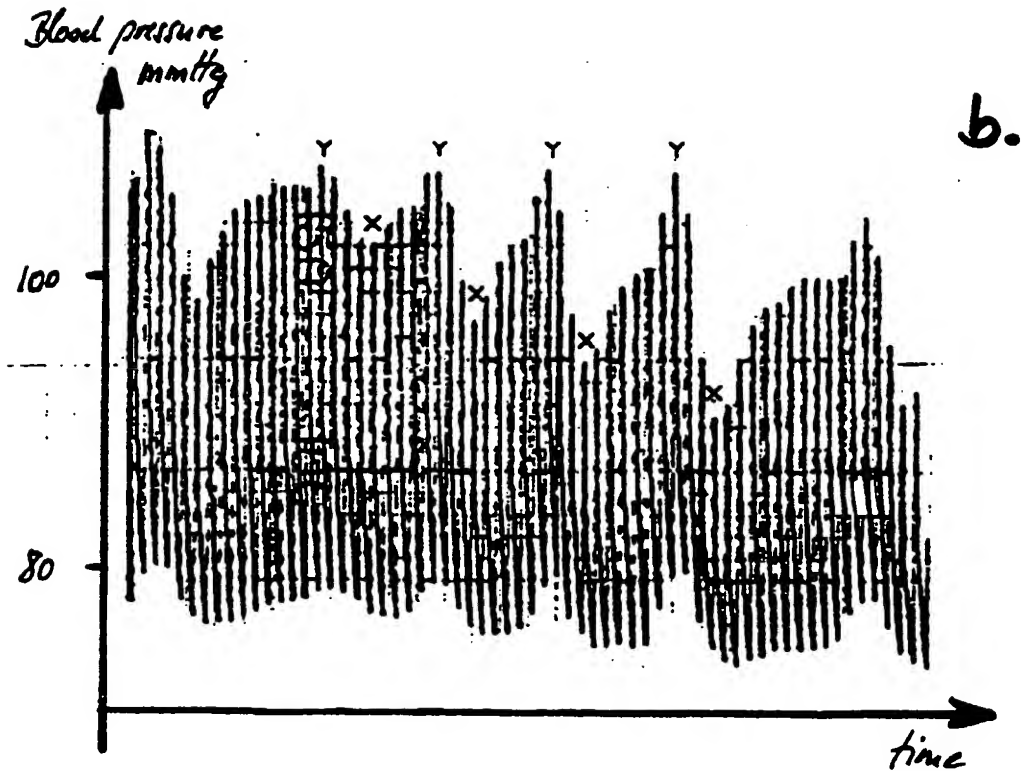
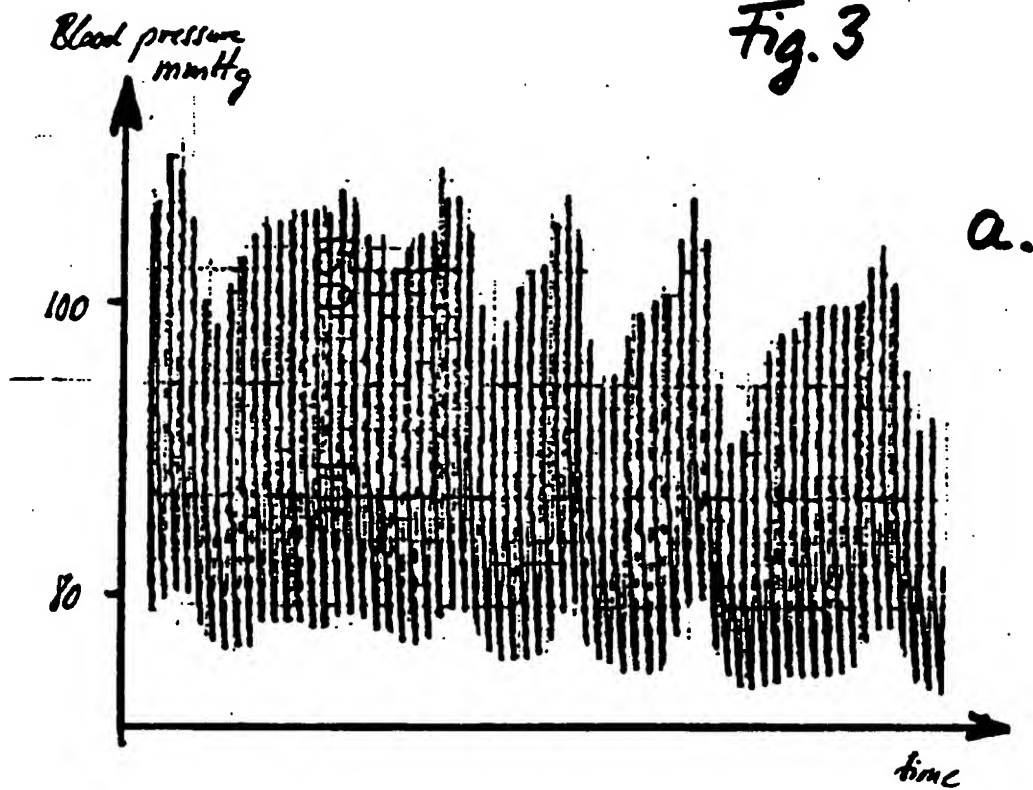
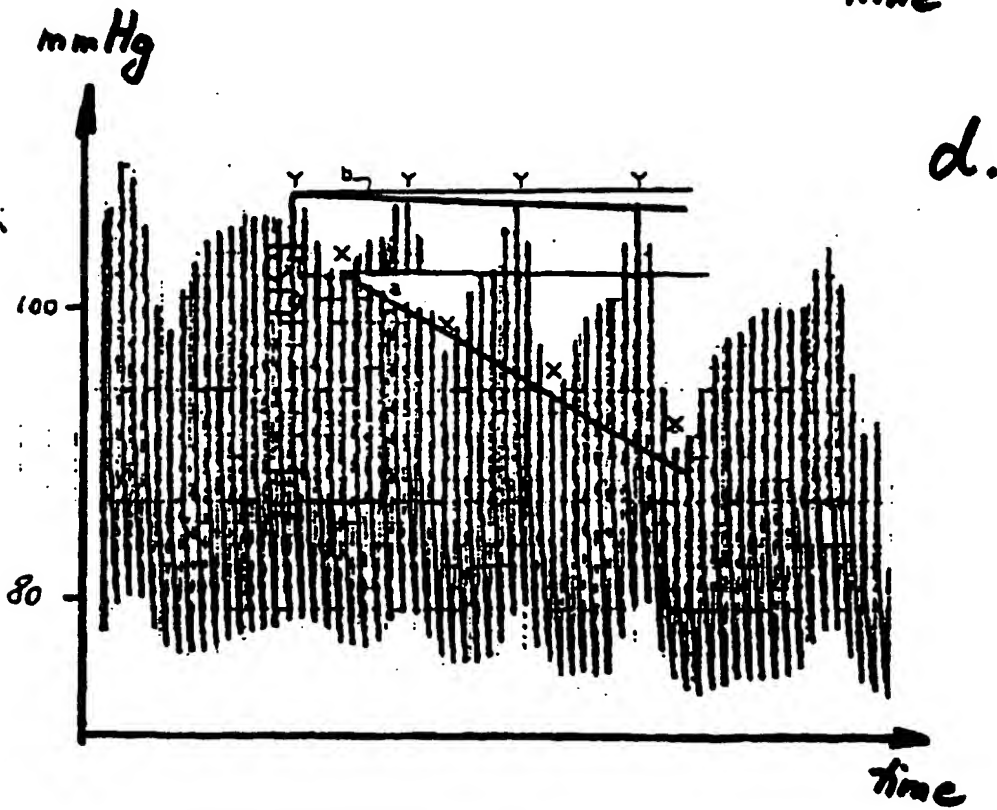
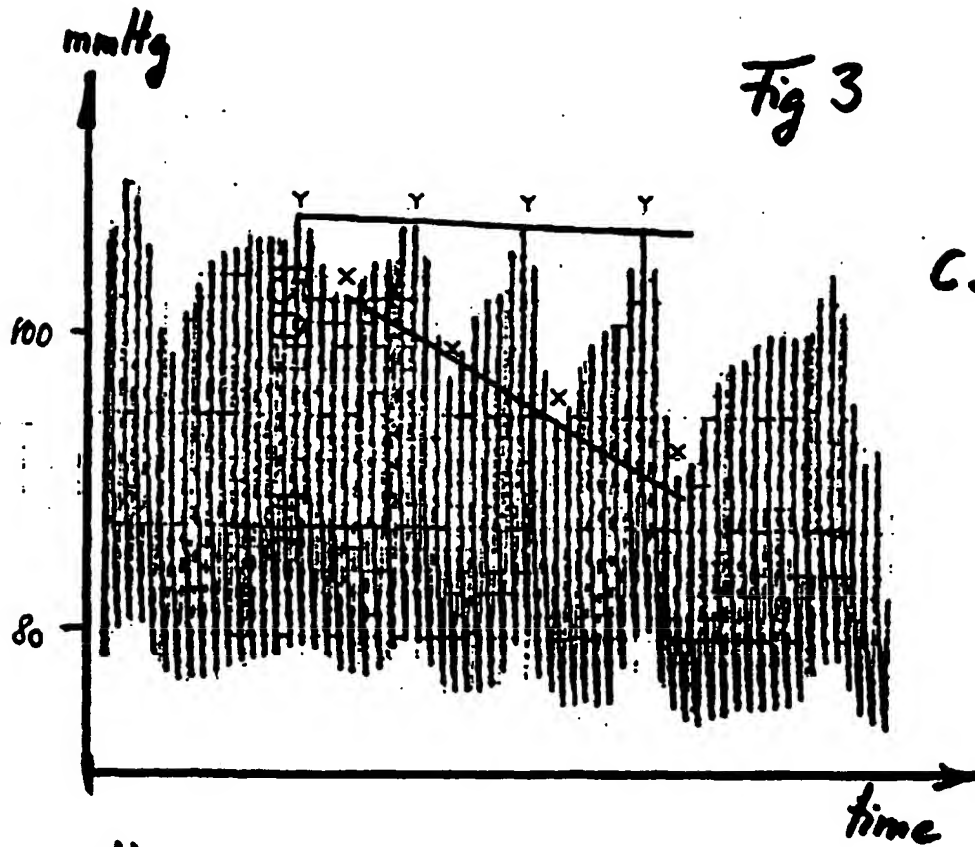


Fig. 2

15

Fig. 3





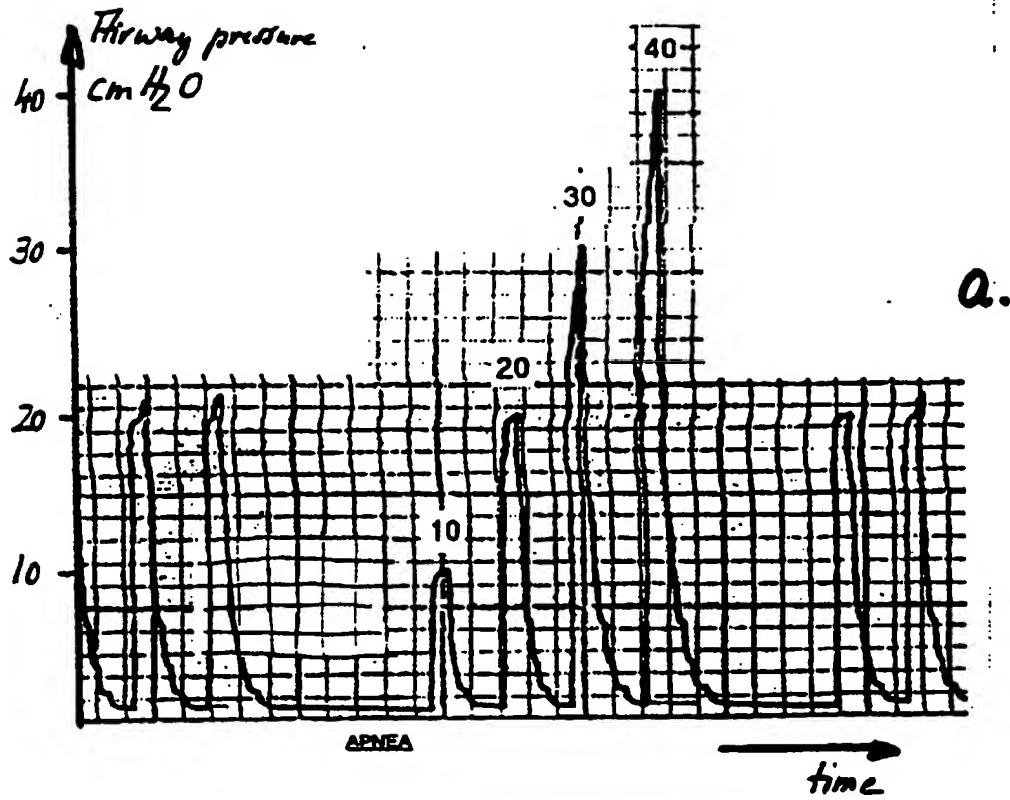
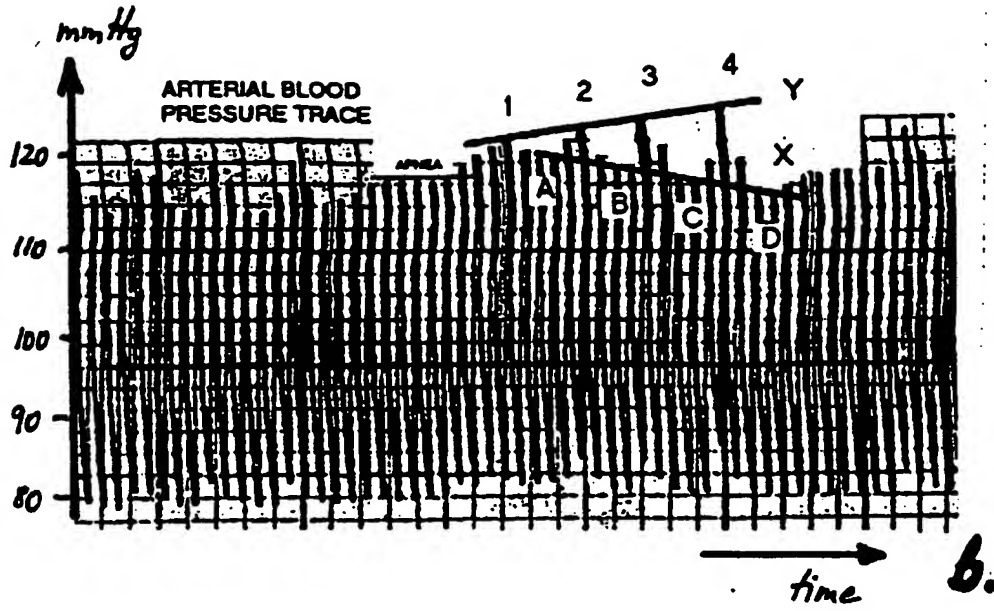
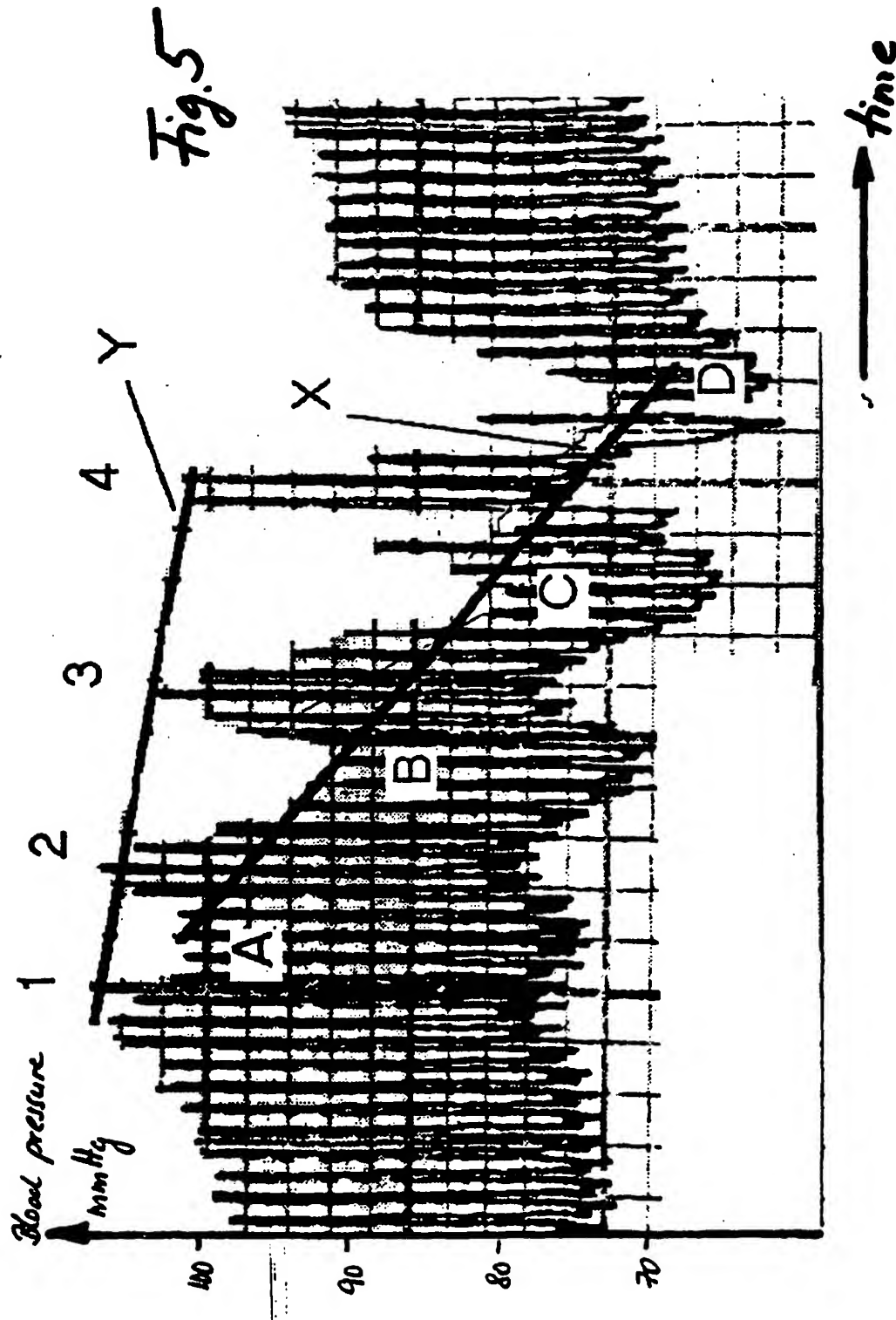


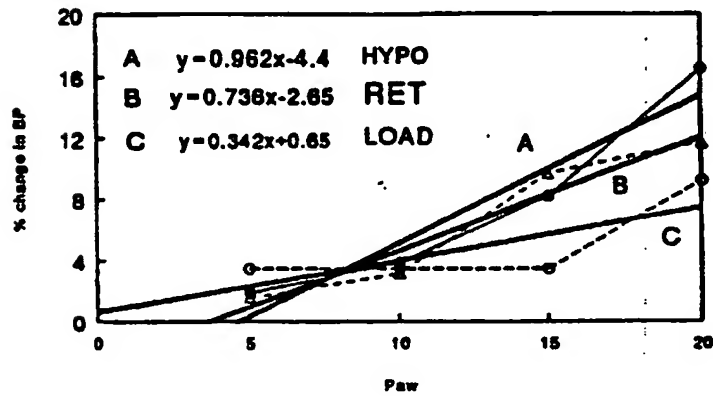
Fig 4



19

RSVT DURING BLEEDING, RETRANSFUSION
AND VOLUME OVERLOAD (dog #1)

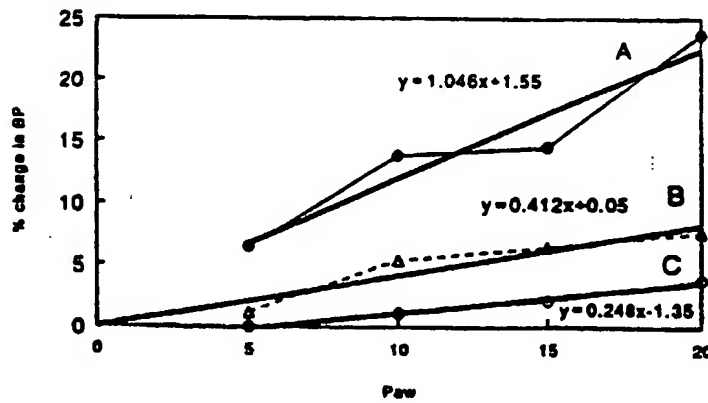
—●— A-HYPOVOLEMI —△— B-RET. —○— C-OVERLOAD



a.

RSVT DURING BLEEDING, RETRANSFUSION
AND VOLUME OVERLOAD (dog #2)

—●— A-HYPOVOL. —△— B-RET. —○— C-LOAD



b.

Fig. 6

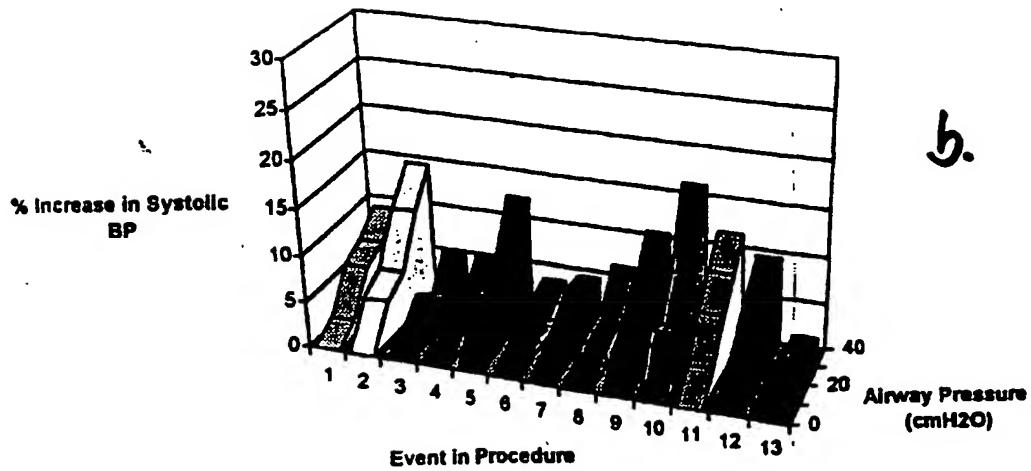
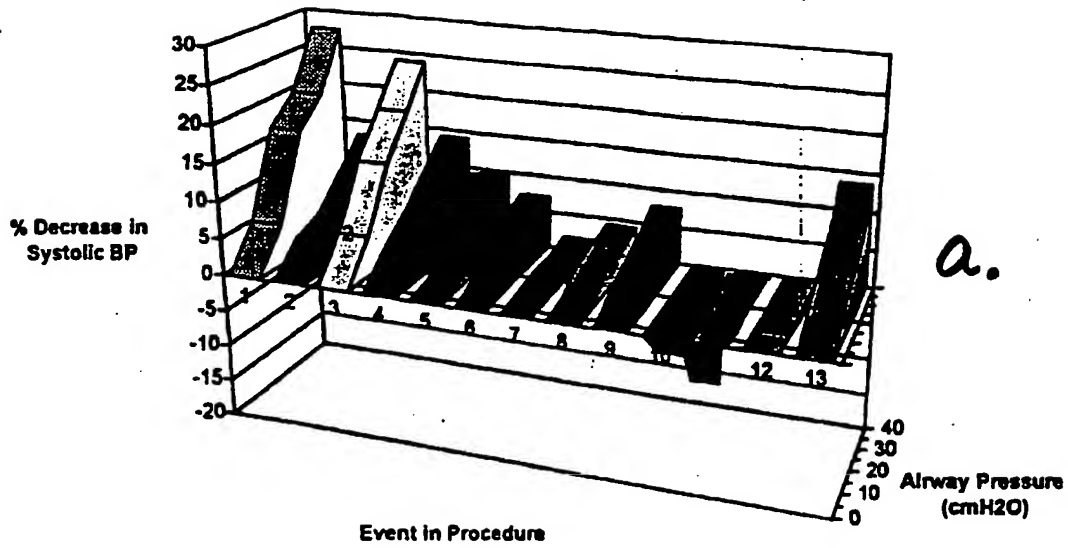


Fig. 7

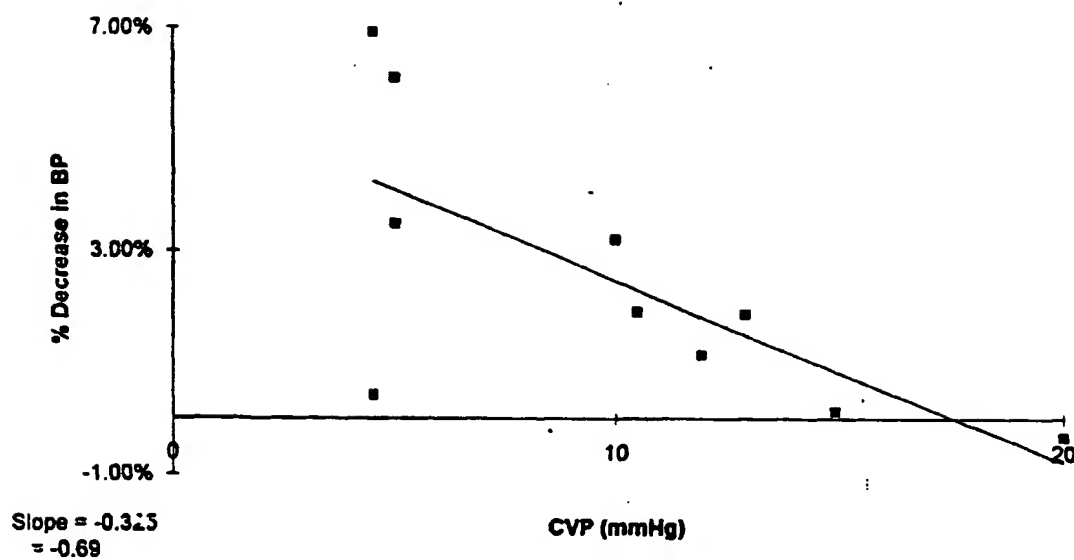


Fig. 8

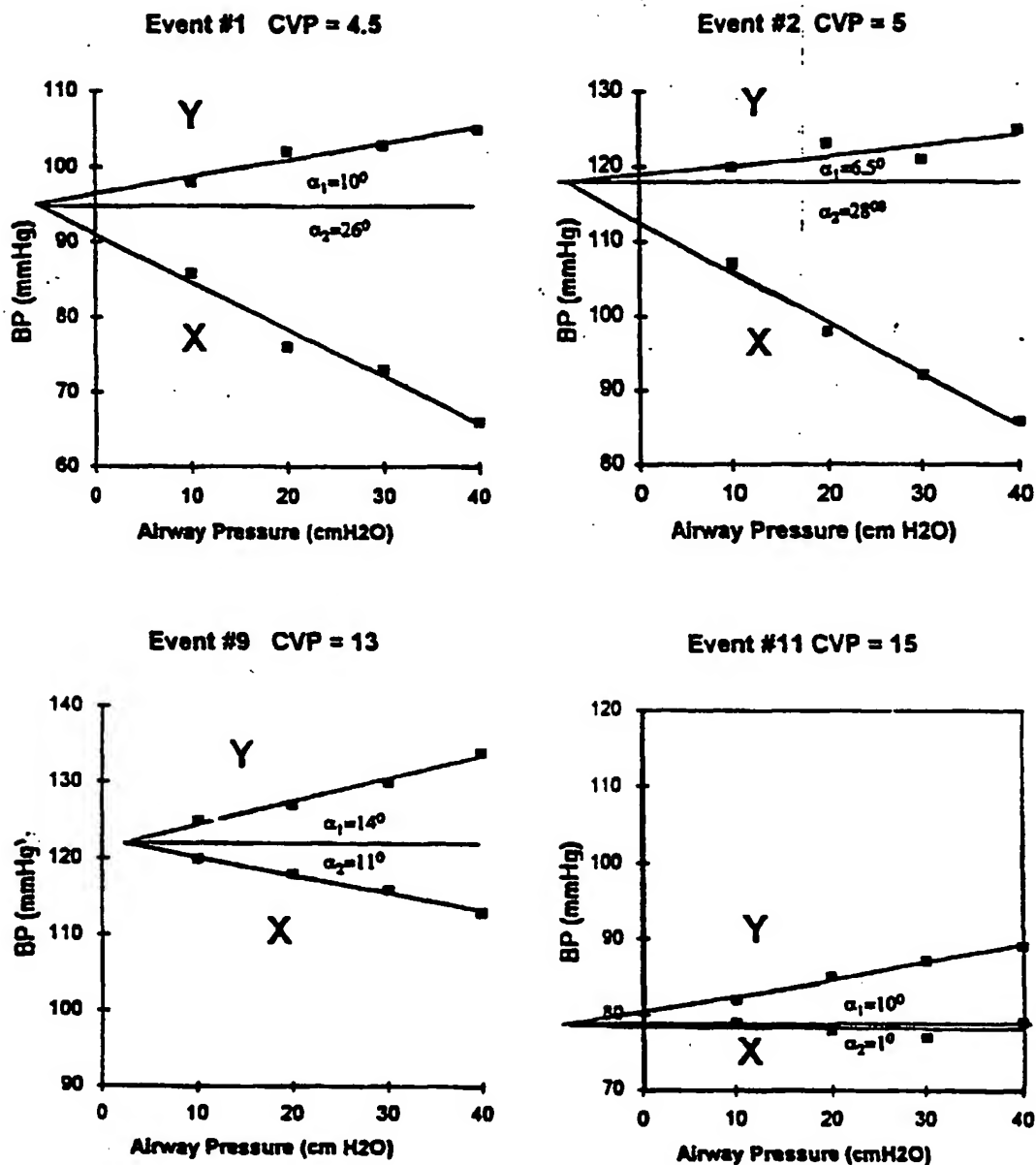


Fig. 9